

101



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,111	11/05/2001	Gerard Bernard O'Beirne	PA-0060	7469

7590 12/08/2004
 Royal N. Ronning, Jr
 Amersham Biosciences
 800 Centennial Avenue
 Piscataway, NJ 08855

EXAMINER

GABEL, GAIENE

ART UNIT	PAPER NUMBER
----------	--------------

1641

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,111

Applicant(s)

O'BEIRNE ET AL.

Examiner

Gailene R. Gabel

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) 2-4 and 14-19 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 5-13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed on 9/20/04 is acknowledged and has been entered. Claims 1 and 5 have been amended. Claims 2-4 and 14-19 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-19 are pending. Claims 1 and 5-13 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step i) remains vague and indefinite in reciting, "support particles ... being adapted for cell growth" because it is unclear how the support particles are modified or adapted to support cell growth.

Claim 1, step ii) remains vague and indefinite in reciting, "cells, adhering to said support particles" because it is unclear if Applicant intends for specific cell populations to form a complex, i.e. attached or bound or adhered, with the support particles.

Specifically, claim 1, step ii) implies, but fails to distinctly define that the cells growing on

support particles in step i) also adhere or attach to the support particles in the process, i.e. adherent cells.

Claim 1, step iv) is indefinite in being redundant in reciting, "the said support particles".

Claim 1, step iv) is vague and indefinite in reciting, "a scintillant substance" because it is unclear if Applicant intends to refer back to the scintillant substance recited in step i) or otherwise, intends use of additional scintillant substance other than that recited in step i). If Applicant intends to refer back to the scintillant substance recite in step i), "a" should be replaced with "the" or "said".

Claim 1, step iii) remains ambiguous in reciting, "said radiolabeled reagent to become associated with said cells" because it is unclear what Applicant intends to encompass in reciting, "associated" with respect to the cells and cellular process. Specifically, claim 1 is confusing because it is unclear what structural and functional cooperative relationship exists between the radiolabeled reagent and the cells and cellular processes therein, in order to thus, allow measurement of cellular process.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1 and 5-13 stand rejected under 35 U.S.C. 102(e) as being anticipated by Jessop (US Patent 6,524,786) for reasons of record.

Jessop discloses scintillation proximity assays performed in multiwell plates wherein a charge-coupled device (CCD) is used in a detection step to image cellular processes in living and growing (proliferating) cells (see Abstract, column 2, line 59 to column 3, line 11, and column 4, lines 4-37). Jessop teaches providing one or more different populations of living, growing, and adherent cells which are attached to support particles (particulates or beads) having surfaces capable of cell growth and carrying a scintillant substance (phosphor). In practice, Jessop teaches introducing the adherent cells attached to scintillant particles in a medium, to massive surfaces such as separate vessels or wells of a microtiter plate (see column 3, lines 12-25 and lines 52-66). Thereafter, radioisotope-labeled reagent is added to the wells so as to monitor uptake (association) of the radioisotope by the growing culture cells in real time or dynamic mode. The radioisotopes include ^3H , ^{125}I , ^{14}C , ^{35}S , ^{56}Ca , ^{33}P , ^{32}P , ^{55}Fe , ^{86}Rb , ^{109}Cd , and ^{51}Cr (see column 3, lines 45-51 and Example 9). Cellular processes are measured by detecting light emission from the scintillant support particles as caused by the

radioactive decay of the radioisotope label (see column 3, lines 26-44). The cellular processes tested include receptor binding assay, uptake, and biochemical response. Different concentrations of radioisotope label are incubated with different samples of cells in reaction vessels (see column 3, lines 64-67 and Examples 1, 6, and 7). Jessop provides that detection step may be performed by scintillation counting (see column 1, lines 47-60).

Response to Arguments

4. Applicant's arguments filed 9/20/04 have been fully considered but they are not persuasive.

A) Applicant argues that claims 1 and 5-13 are not anticipated by Jessop because Jessop fails to teach or even suggest that the populations of cells are "growing on support particles" as currently recited in claim 1. Applicant contends that there is no disclosure or suggestion of growing cells directly upon the support particles.

Contrary to Applicant's argument, Jessop specifically teaches growing adherent cells on support particles in column 2, line 66 to column 3, line 25 and Example 9. Jessop provides in column 2, line 66 to column 3, line 25, that living cells attached to the surface of scintillant support particles carrying the phosphor are studied, measured, or assayed chemically or biochemically. The surface may be particulate, i.e. particles or beads, or they may be wall of a vessels or wells of a multiwell plate. Jessop exemplifies application of the assay method with growing or proliferating, adherent culture cells

seeded on surface of wells of a Cytostar-T plate in Example 9. Accordingly, claims 1 and 5-13 are anticipated by the Jessop reference.

5. No claims are allowed.

Remarks

6. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Clapper et al. (US Patent Number 5,512,474) discloses cell culture support containing cell adhesion factor and a positively charged molecule. Example 11 shows cell attachment and growth on Cytodex beads.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

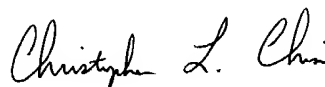
Art Unit: 1641

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
December 2, 2004



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641

12/6/04